Express Mail Label No.: EV 0732US Wall Date of Deposit: August 28, 2002

Attorney Docket No. 21402-042 (CURA-342)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Rastelli, et al

SERIAL NUMBER:

10/016,253

EXAMINER:

Not Yet Assigned

FILING DATE:

December 10, 2001

ART UNIT:

1614

For:

AUG 2 8 2002

METHODS OF DETECTING AND TREATING TUBEROUS SCLEROSIS

COMPLEX ASSOCIATED DISORDERS

U. S. Patent and Trademark Office

BOX SEQUENCE

P. O. Box 2327

Arlington, VA 22202

30023

PATENT TRADEMARK OFFICE

TRANSMITTAL LETTER

Enclosed herewith are the following for the above-identified non-provisional patent application:

- 1. Petition for Extension of Time (1 pg)
- 2. Copy of Notice to File Missing Parts (2 pgs);
- 3. Check No. 13868 in the amount of \$130.00 to cover the Surcharge;
- 4. Preliminary Amendment and Response to Notice to File Missing Parts (2 pgs);
- 5. Copy of Combined Declaration and Power of Attorney (3 counterparts) (9 pgs);
- 6. Substitute Specification (78 pgs);
- 7. Statement in Support of Substitute Specification (1 pg);
- 8. Check No. 13869 in the amount of \$1,960.00 to cover extension fee; and,
- 9. Computer Readable Form copy of the "Sequence Listing" (1 diskette);
- 10. Statement in Support of Computer Readable Form (1 pg.);
- 11. Paper Copy of "Sequence Listing" (10 pgs.)
- 12. Return postcard.

The Commissioner is hereby authorized to charge any fee that may be due, or to credit any overpayment, to Deposit Account No. 50-0311 (Reference No. 21402-042 (CURA-342)). A duplicate copy of this transmittal letter is enclosed.

Respectfully submitted.

Ivor R. Elrifi, Reg. No. 39,529

Attorney for Applicants

c/o MINTZ, LEVIN
One Financial Center

Boston, Massachusetts 02111

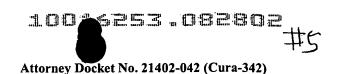
Tel: (617) 542-6000

Fax: (617) 542-2241

Dated: August 28, 2002

Express Mail Label No.: E3 80732US

Pate of Deposit: August 28, 2002





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EICANTS:

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Commissioner for Patents and Trademarks Washington, D.C. 20231

STATEMENT IN SUPPORT OF SUBSTITUTE SPECIFICATION

Pursuant to 37 CFR 1.125(b)(1), I hereby state that the content of the substitute specification and the specification filed on December 10, 2001 are the same. Applicants hereby submit this substitute specification in response to the Notice to File Missing Parts mailed on January 28, 2002, which specifically requested a substitute specification in compliance with 37 C.F.R. §1.52. The correction of the margins is the only amendment made to the specification at this time. Thus, this submission includes no new matter.

Applicants believe that no additional fees are required for the filing of the present submission. However, the Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment, to Deposit Account No. 50-0311, Ref. No. 21402-042 (Cura-342).

Respectfully submitted,

August 28, 2002

Ivor R. Elrifi, Reg. No. 39,529

Attorneys for Applicants

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TRA 1705568v1

Express Mail Label No. EV058280732US Date of Deposit: August 28





United States Patent and Trademark Office

COMMISSIONER FOR PATENTS UNITED STATES PATENT AND TRADEMARK OFFICE WASHINGTON, D.C. 20231

www.uspto.gov FIRST NAMED APPLICANT APPLICATION NUMBER ING/RECEIPT DATE ATTORNEY DOCKET NUMBER 12/10/2001 10/016,253 Luca Rastelli 21402-042 (Cura 342) **CONFIRMATION NO. 4494**

RECEIVED

FORMALITIES LETTER

OC000000007378548

GLOVSKY AND POPEO, P.C Done By One Financial Center Boston, MA 02111 Data Entry ocket Entry

Docket Cross Off

Previously Entered

MUNTZ, LEVIN, COHN, T

MINTZ LEVIN, BOSTON PATENT DOCKET DEPT.

FEB 0 1 2002

Date Mailed: 01/28/2002

☐ No Docketing Req. ☐ ELITE

FILED UNDER 37 CFR 1.53(b)

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below. however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(I) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- The balance due by applicant is \$ 130.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

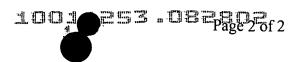
- A substitute specification in compliance with 37 CFR 1.52 because:
 - Papers contain improper margins. Each sheet must have a left margin of at least 2.5 cm (1") and top, bottom and right margins of at least 2.0 cm (3/4")

This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention 🖻 is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant

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desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase Patentin Software, call (703) 306-2600
- For Patentin Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

A copy of this notice MUST be returned with the reply.

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 1 - ATTORNEY/APPLICANT COPY